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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------|------------------|
| 10/802,520 | 03/16/2004 | Eric Leopold | MICRU:68082 | 3981 |
| 24201 7590 03/20/2007 FULWIDER PATTON LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE, TENTH FLOOR LOS ANGELES, CA 90045 | | | EXAMINER POUS, NATALIE R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3731 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 03/20/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|-------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 10/802,520 | Applicant(s) LEOPOLD ET AL. | |
| | Examiner Natalie Pous | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/16/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Regarding objection to the IDS

Applicant's arguments, see page 5, filed 12/1/06, with respect to the IDS have been fully considered and are persuasive. The objection to the IDS has been withdrawn.

Regarding Diaz

Applicant argues that Diaz is not entitled to the priority date of January 10, 2001 for the limitation wherein "a longitudinal slot is formed in the upper wall of the elongated member, leaving up to about 10cm with no slot" under 102. As described in the previous office action, the non-provisional application Diaz 2004/0087964 does not introduce new matter, it simply further clarifies and explains aspects introduced by the provisional application 60/260742. Thus, after further consideration, examiner sustains that Diaz 2004/0087964 is entitled to the priority date of the provisional application 1/10/2001. Regarding the addition of limitation "the sheath being attached to a segment of the flexible pusher member," upon further consideration, examiner concludes that Diaz meets this limitation in that when the sheath is disposed over the flexible pusher member, it is attached to it.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

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subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 24-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz as a matter of design choice and further in view of Ahmed (5293713) and further as a matter of design choice.

Diaz teaches a device comprising the following:

- A sheath (50) in combination with a vasoocclusive device (50)
- the vasoocclusive device including an assembly of a flexible pusher member (44) and an embolic coil (44) that is adapted to be inserted into a portion of a vasculature for occluding a portion of the vasculature for use in interventional therapy and vascular surgery, the sheath comprising:
 - a hollow, elongated tubular member having opposing upper and lower walls,
 - opposing side walls (12)
 - a longitudinal interior channel (14)
 - the sheath being attached to a segment of the flexible pusher member

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- a longitudinal slot (36) formed in the upper wall of the elongated tubular member and
- extending a majority of the length of elongated tubular member leaving up to about 10cm with no slot (Page 4, paragraph 42)
- the slot having opposing sides with inner side surfaces extending through the upper wall of the elongated tubular member leading to the interior channel (12) permitting introduction of the vasoocclusive device into the interior channel
- wherein the outside diameter is approximately .003 inches, and wherein the inside diameter is slightly greater than that of a deployment catheter (Page 4, paragraph 42), corresponding to the lower wall of the hollow, elongated tubular member (12) being about 0.002 to 0.004 inches thick to allow the opposing sides of the slot of the hollow, elongated tubular member to flex outwardly to allow the slot to open to accept the vasoocclusive device (Page 2, paragraph 14).
- wherein the hollow, elongated tubular member is formed from a polymer material with a durometer in the range of about 50D and 70D (page 4, paragraph 42).

High-density polyethylene is a type of thermoplastic polymer and has a durometer of between 61D and 63D, falling in the disclosed range.

Diaz fails to teach a v-shape configured guide. Ahmed teaches the use of angled winged flanges in order to enhance guiding the element as the element is pushed through the opening (Col. 2 lines 68-70). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide Diaz with the winged

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flanges as taught by Ahmed in order to enhance guiding the element as the element is pushed through the opening.

Ahmed fails to disclose the size of the interior angle between the wings, however, Ahmed does disclose that it should be at least thirty degrees, and further the angle used is sufficient to perform the function of a guide as illustrated in figure 2. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the angles of the opening between 110 to 150 degrees, a working range as disclosed by the applicant, since the device as disclosed by Ahmed performs equally well as a guide without a specific angle range. Further, it has been held that where the general condition of the claim are disclosed in the prior art, discovering the optimum workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
1/30/07


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
